K031420

AUG 20 2003

10. 510(k) Summary of Safety and Effectiveness

Submitter

S & C Polymer GmbH
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Dr. Christian Boettcher (Contact Person)

Date Summary Prepared: April 2003

Device Name:

• Trade Name	S & C-Bracket Adhesives
• Common Name	Bracket Adhesives
• Classification Name	Adhesive, Bracket and tooth conditioner, Resin (per 21 CFR § 872.3750):

Devices for which Substantial Equivalence is claimed:

LC BRACKET ADHESIVE:	**IVOCLAR VIVADENT (Manufacturer)** *Heliosit Orthodontic (Product)*
DC BRACKET ADHESIVE: **NO MIX BRACKET ADHESIVE:**	**RELIANCE ORTHODONTICS PRODUCTS (Manufacturer)** *Rely a Bond (Product)*

Device Description:

LC Bracket Adhesive:	Light cure bracket adhesive for the direct bonding of transparent glass ceramic brackets, plastic brackets and metal brackets.
DC Bracket Adhesive:	Dual cure bracket adhesive for the direct bonding of glass ceramic brackets, plastic brackets and metal brackets
No Mix Bracket Adhesive:	One step bracket adhesive for the direct bonding of metal-, ceramic and plastic brackets.

Intended Use of the Device:

The Bracket Adhesives are used for the bonding of brackets.

Substantial Equivalence:

The products are substantially equivalent to other legally marketed devices in the United States.

The Light Cure Bracket Adhesive marketed by Ivoclar Vivadent (Heliosit Orthodontic) functions in a manner similar to and is intended for the same use as the product marketed by S & C Polymer (LC Bracket Adhesive).

The No Mix Bracket Adhesive marketed by Reliance Orthodontic Products (Rely a Bond) functions in a manner similar to and is intended for the same use as the product marketed by S & C Polymer (DC Bracket Adhesive, No Mix Bracket Adhesive).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2003

Dr. Christian Boettcher
Regulatory Compliance Officer
S & C Polymer
Robert-Bosh-Strasse 5
D-25335 Elmshorn
GERMANY

Re: K031420
Trade/ Device Name: S&C- Bracket Adhesives
Regulation Number: 872.3750
Regulation Name: Bracket Adhesive Resin and tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: April 29, 2003
Received: May 5, 2003

Dear Dr. Boettcher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA,
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

9. Statement of Indications for Use

510(k) Number (if known): K031420

Device Name:

1. LC Bracket Adhesive
2. DC Bracket Adhesive
3. No Mix Bracket Adhesive

Indications for Use:

1. Light cure bracket adhesive for the direct bonding of transparent glass ceramic brackets, plastic brackets and metal brackets.

2. Dual cure bracket adhesive for the direct bonding of glass ceramic brackets, plastic brackets and metal brackets.

3. One step bracket adhesive for the direct bonding of metal-, ceramic and plastic brackets.

Kevin Mulloy for MSN

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031420

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: or Over-The-Counter Use: